34. The pharmaceutical formulation according to claim 24 wherein 30-35% of the active ingredient is combined with the first polymer or mixture of polymers, 30 to 35% is combined with the second polymer or mixture of polymers and 30 to 35% is combined with the third polymer or mixture of polymers.

REMARKS

Reconsideration and removal of the grounds for rejection are respectfully requested. Claims 2-22 were in this application, claim 2-22 have been canceled and new claims 23-34 have been added.

Claims 2-22 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite as the claims were in generally narrative form and not in conformance with current U.S. practice. So as to clarify the claims as relates to the applicant's invention, all of the claims were reviewed and new claims 23-34 prepared in conformance with current U.S. practice. In amending the claims, each of the comments which the examiner made in the rejection was considered in reformulating the corresponding new claims. Consequently, it is believed that this rejection has been rendered moot by this amendment.

From a review of the specification and examples, it is clear that the applicant's invention is a pharmaceutical formulation, as described on page 4, lines 11 and 15, for a multiphasic release of an active ingredient for treating inflammatory bowel disease (page 4, lines 21-22). In conformance with the examples, the active ingredient is in a solid form in an amount sufficient to treat inflammatory bowel disease, with the active ingredient separated into a plurality of portions. (See page 10, lines 12-14). Each of the plurality of portions is combined with one of a corresponding plurality of pH dependent soluble polymers or mixtures of polymers each of the

plurality of polymers or mixture of polymers having a different pH solubility. (See example 4, 4.1, 4.2, 4.3). The separate portions of active ingredient and combined polymer or mixture of polymers are mixed together to form the pharmaceutical formulation of the invention where the active ingredient portions are releasable at each pH value corresponding to each of the different pH solubilities, thereby providing a multiphasic release of the active ingredients. (See example 4.4, page 11, line 14 through table 9, example 5, etc.). Consequently, new claim 23 and the claims dependent therefrom correspond to the subject matter of the application and no new matter is included by these amendments.

Claims 2, 3, 6, 8, 15, 16, 18, 19 and 21 were rejected under 35 U.S.C. §102(e) as being anticipated by Yajima et al, U.S. patent no. 5,972,373. To have anticipation, each and every element of the claim must be found in a single prior art reference. W.L. Gore and Associates v. Garlock, Inc., 721 F.2d 1540 (Fed. Cir. 1983).

Yajima et al describes a taste masking pharmaceutical composition for oral administration. However, Yajima fails to disclose the pharmaceutical formulation of the applicant's invention which provides multiphasic release of an active ingredient utilizing a plurality of active ingredient portions combined with a corresponding plurality of pH dependent soluble polymers or mixtures of polymers having different pH solubility and consequently, as each and every element of these claims are not found in Yajima, claim 23 and the claims dependent therefrom are not anticipated by Yajima.

Claims 2, 5, 6-10, 18 and 21 were rejected under 35 U.S.C. §102(b) as being anticipated by Kjorn et al, U.S patent no. 4,713,248. Claim 23 and the claims dependent therefrom are not anticipated by Kjorn which contains an active ingredient as a core within a pair of film layers

t[illegible]reover, which delays and controls diffusion through an inner film layer to confer a degree of controlled release. (Col. 2, lines 38-60). However, the applicant's invention is not directed to film diffusion of an active ingredient and as each and every element of the claims is not found in Kjorn et al, claims 23 and the claims dependent therefrom are not anticipated thereby.

Claims 2, 4, 6, 7, 10, 13-15, 18 and 21 were rejected as being anticipated by Shah et al, U.S. patent no. 5,482,718. However, with reference to Fig.1, it is clear that utilization of an enteric coating and outer layer matrix are used to prevent drug delivery within the stomach or intestine, so that the drug is released only in the colon. Fig. 2 shows the absence of any release prior to arrival at the colon. On the other hand, the applicant's invention utilizes a system which releases portions of the active ingredient during transport through the intestinal tract in accordance with the differing pH's. As the plurality of active ingredient portions combined with a corresponding plurality of pH dependent soluble polymers or mixture of polymers are not found in Shah et al, claim 23 and the claims dependent therefrom are not anticipated thereby.

Claims 19 and 20 were rejected under 35 U.S.C. §103(a) as being obvious over Shah et al '718.

It is not within the framework of 35 U.S.C. §103 to pick and choose from the prior art only so much as will support a holding of obviousness to the exclusion of other parts necessary for a full appreciation of what the prior art teaches or suggests, as hindsight is not the test. In re Wesslau, 353 F.2d 238, (CCPA 1965). There can be no teaching or suggestion if the reference teaches away from the applicant's invention. In re Fine, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). A reference may be said to teach away when the person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the application or would

be led in a divergent direction from the path which was taken by the applicant. In re Gurley, 31 U.S.P.Q. 2d 1130, 1131 (Fed. Cir. 1994).

Shah et al clearly teaches away from the applicant's invention as Shah is directed to protecting the active ingredient from release in different areas of the intestinal tract so that all of the active ingredient is released in the colon. On the other hand, the applicant's invention has segregated the active ingredients into portions for a multiphasic release in accordance with the solubility of a corresponding polymer or mixture of polymers associated with the portion of the active ingredient. As there is no teaching or suggestion in Shah for producing a pharmaceutical formulation in accordance with the present invention, claims 19 and 20, now claims 33 and 34, are not obvious in view of Shah.

Based on the above amendments and remarks, reconsideration and allowance of the application is respectfully requested. However should the examiner believe that direct contact with the applicant's attorney would advance the prosecution of the application, the examiner is invited to telephone the undersigned at the number given below.

Respectfully submitted,

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